Remarks

This Amendment is being filed in response to the Official Action mailed in this application on July 27, 2005. A request for a one-month extension of time accompanies this Amendment. By this Amendment, claim 1 is amended and claims 1 and 13-16 remain pending in this application. Reconsideration of this application is respectfully requested in view of the above amendments and further in view of the following remarks.

Claims 1 and 13-16 were rejected under 35 USC §112, 1st paragraph, as allegedly lacking enablement.

Although the issue presented in the rejection is whether applicant has enabled the invention, applicant maintains that the basis of the rejection is an assertion that the application fails to demonstrate that the invention works. Thus, the 35 U.S.C. § 112 rejection is simply a rejection under 35 U.S.C. § 101 in the guise of a rejection under 35 U.S.C. § 112.

In any event, page 10 of the action summarizes seven pages of rejection:

"The quantity of experimentation needed to make or use the present invention includes trial and error experimentation to **elucidate** the mechanism of cell transformation *in vitro* or *in vivo* by applying nucleic acid to cells first, then administering a pliable, adhesive fibrin gel to said cells, trial and error experimentation to determine how to **increase or enhance cell transformation efficiency** *in vitro* and *in vivo* by the claimed method, trial and error experimentation to determine how to administer a nucleic acid to the target cell on the surface of a subject or to the target cell at various locations inside the body of a subject, such as liver, kidney, lung, intestine, stomach, etc., trial and error experimentation to determine how to administer the pliable and adhesive fibrin gel to the target cell on the surface of a subject or to the target cell at various locations inside the body of a subject, such as liver, kidney, lung, intestine, stomach, etc., via various administration routes before the fibrin gel get polymerized so as to transform the target cell with said nucleic acid or to **increase cell transformation efficiency**, and trial and error experimentation to transform target cells with the claimed method such that therapeutic effects can be obtained for a particular disease or disorder *in vivo*" (emphasis added).

In a previous rejection, the Office acknowledged that transforming a cell *in vivo* was enabled when done with a stent or balloon catheter, and it was acknowledged in a final rejection that transforming a cell *in vitro* was enabled. Now the Office asks the applicant to explain or "elucidate" the mechanism of cell transformation. Applicant respectfully notes that even the most skilled in the art can offer no more than informed speculation on the mechanism of transformation and such is

not a requirement of the patent law. That is, the patent law does not require an applicant to understand the theory of operation for his or her invention.

The action suggests that applicant's invention must "increase or enhance cell transformation efficiency". That is not a requirement of the patent law either.

The action further indicates that applicant must show every possible way to administer his invention. And that is not a requirement of the patent law.

Accordingly, applicant submits that this rejection, whether under 35 U.S.C. §112 or §101, is without merit.

Applicant also notes that the rejection criticizes the title of the application. The title of the application was amended at least a year ago. Moreover, the rejection essentially asserts that "[t]he claims read on gene therapy *in vivo*", and since gene therapy was unpredictable at the time of the invention, the claims lack enablement. However, the claims are not directed to gene therapy *per se*. Rather, the claims are directed to transforming a cell. The rejection acknowledges that "progress has been made" in many respects.

For all these reasons, it is submitted that this rejection should be withdrawn.

Claims 1 and 13-16 were also rejected under 35 U.S.C. §112, second paragraph. Although it is believed the claims were clear as written, applicant has amended the claims in an attempt to satisfy the concerns noted in the action and to advance the prosecution of this application. Accordingly, applicant submits that this rejection should be withdrawn.

In view of the foregoing, reconsideration of this application and allowance of claims 1 and 13-16 are all earnestly solicited.

Respectfully submitted,

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